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|                                  |                   |                      |                         | <u> </u>         |
|----------------------------------|-------------------|----------------------|-------------------------|------------------|
| APPLICATION NO.                  | FILING DATE       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
| 10/083,424                       | 02/26/2002        | Jin-Kyoo Kim         | 5294-000006             | 6744             |
| 27572                            | 7590 08/06/2003   |                      |                         |                  |
| HARNESS, DICKEY & PIERCE, P.L.C. |                   |                      | EXAMINER                |                  |
| P.O. BOX 828                     | 3                 |                      | HELMC LAD               | DV DONALD        |
| BLOOMFIEL                        | D HILLS, MI 48303 |                      | HELMS, LARI             | RY RONALD        |
|                                  |                   |                      | ART UNIT                | PAPER NUMBER     |
|                                  |                   |                      | 1642                    | 7                |
|                                  |                   |                      | DATE MAILED: 08/06/2003 |                  |
|                                  |                   |                      |                         |                  |
|                                  |                   |                      |                         | ,                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application N .           | Applicant(s)  |  |  |  |  |
|---|---------------------------|---|--|--|--|--|
|   | 10/083,424                | KIM ET AL.  |  |  |  |  |
| Office Action Summary   | Examiner                  | Art Unit  |  |  |  |  |
|   | Larry R. Helms            | 1642  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address   |                           |   |  |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM   |                           |   |  |  |  |  |
| THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |                           |   |  |  |  |  |
| 1) Responsive to communication(s) filed on _  | <u> </u>                  |   |  |  |  |  |
| 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ 1   | This action is non-final. |   |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims  |                           |   |  |  |  |  |
| 4)⊠ Claim(s) <u>1-22</u> is/are pending in the application.   |                           |   |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |                           |   |  |  |  |  |
| 5) Claim(s) is/are allowed.   |                           |   |  |  |  |  |
| 6) Claim(s) is/are rejected.  |                           |   |  |  |  |  |
| 7) Claim(s) is/are objected to.   |                           |   |  |  |  |  |
| 8) Claim(s) 1-22 are subject to restriction and/or election requirement.  |                           |   |  |  |  |  |
| Application Papers  |                           |   |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |                           |   |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |                           |   |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |                           |   |  |  |  |  |
| 11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.   |                           |   |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |                           |   |  |  |  |  |
| 12)☐ The oath or declaration is objected to by the Examiner.  |                           |   |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |                           |   |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |                           |   |  |  |  |  |
| a) All b) Some * c) None of:  |                           |   |  |  |  |  |
| 1. Certified copies of the priority documents have been received.   |                           |   |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |                           |   |  |  |  |  |
| <ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |                           |   |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |                           |   |  |  |  |  |
| a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.   |                           |   |  |  |  |  |
| Attachment(s)   |                           |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)   | 5) 🔲 Not                  | rview Summary (PTO-413) Paper No(s) ce of Informal Patent Application (PTO-152) er: |  |  |  |  |
| U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)  Office   | Action Summary            | Part of Paper No. 7   |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1, 2, 7, 13 in part and claim 8, drawn to a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:18 and 26 respectively, classified in class 530, subclass 387.3.
  - II. Claims 1, 2,7, 13 in part and claim 9, drawn to a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:20 and 28 respectively, classified in class 530, subclass 387.3.
  - III. Claims 1, 2,7, 13 in part and claim 10, drawn to a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:22 and 30 respectively, classified in class 530, subclass 387.3.
  - IV. Claims 1, 2,7, 13 in part and claim 11, drawn to a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:24 and 32 respectively, classified in class 530, subclass 387.3.
  - V. Claims 1, 2,7, 13 in part and claim 12, drawn to a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:38 and 40 respectively, classified in class 530, subclass 387.3.
  - VI. Claims 3-6, 14, 20-22 in part and claim 15, drawn to DNA encoding a heavy chain and light chain and a scFv comprising the heavy chain and

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light chain of SEQ ID NO:18 and 26 respectively wherein the nucleic acids are SEQ ID NO:17 and 25, respectively, classified in class 536, subclass 23.53.

- VII. Claims 3-6, 14, 20-22 in part and claim 16, drawn to DNA encoding a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:20 and 28 respectively wherein the nucleic acids are SEQ ID NO:19 and 27, respectively, classified in class 536, subclass 23.53.
- VIII. Claims 3-6, 14, 20-22 in part and claim 17, drawn to DNA encoding a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:22 and 30 respectively wherein the nucleic acids are SEQ ID NO:21 and 29, respectively, classified in class 536, subclass 23.53.
- IX. Claims 3-6, 14, 20-22 in part and claim 18, drawn to DNA encoding a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:24 and 32 respectively wherein the nucleic acids are SEQ ID NO:23 and 31, respectively, classified in class 536, subclass 23.53.
- X. Claims 3-6, 14, 20-22 in part and claim 19, drawn to DNA encoding a heavy chain and light chain and a scFv comprising the heavy chain and light chain of SEQ ID NO:38 and 40 respectively wherein the nucleic acids

are SEQ ID NO:37 and 39, respectively, classified in class 536, subclass 23.53.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-X represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acid of Groups VI-X and the scFv of Groups I-V are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the heavy and light chains and the scFv are made by translation of mRNA. Furthermore, the polynucleotide can be used for hybridization screening or expression and the scFv antibody can be used to immunopurify the antigen, for example. The heavy chains and the light chains and the scFv comprising each heavy and light chain are distinct because each heavy chain is distinct and each light chain is distinct and art on one scFv would not be art on the others. In addition, it would require a separate search of each pair of heavy and light chains that make each distinct scFv. A similar distinction can be made for each DNA that encodes the heavy and light chains that make up each distinct scFv. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-X are patentably distinct.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and/or different classifications, restriction for examination purposes as indicated is proper.

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- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D., whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.
- 6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

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Respectfully, Larry R. Helms Ph.D. 703-306-5879

> LAPRY R. HELMS, PH.D DOTHARY EXAMINER